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DEPARTMENT OF HEALTH AND HUMAN SERVICES

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Certifier A. Corbin

Food and Drug Administration

21 CFR Parts 510 and 524

Ophthalmic and Topical Dosage Form New Animal Drugs; Triamcinolone Spray

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect approval of a new animal drug application (NADA) filed by RMS Laboratories, Inc. The NADA provides for use of triamcinolone topical spray in dogs for the control of pruritus associated with allergic dermatitis.

DATES: This rule is effective [*insert date of publication in the* **Federal Register**].

FOR FURTHER INFORMATION CONTACT: Melanie R. Berson, Center for Veterinary Medicine (HFV–110), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–7543, e-mail: mberson@cvm.fda.gov.

SUPPLEMENTARY INFORMATION: RMS Laboratories, Inc., 1903 East First St., Vidalia, GA 30474, filed NADA 141–210 that provides for use of GENESIS (triamcinolone acetonide) Topical Spray in dogs for the control of pruritus associated with allergic dermatitis. The NADA is approved as of November 4, 2002, and the regulations are amended in part 524 (21 CFR part 524) by adding new § 524.2482 to reflect the approval. The basis of approval is discussed in the freedom of information summary.

NADA 141-210

NFR-1

In addition, RMS Laboratories, Inc., has not been previously listed in the animal drug regulations as a sponsor of an approved application. At this time, 21 CFR 510.600(c) is being amended to add entries for the firm.

In accordance with the freedom of information provisions of 21 CFR part 20 and 514.11(e)(2)(ii), a summary of safety and effectiveness data and information submitted to support approval of this application may be seen in the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, between 9 a.m. and 4 p.m., Monday through Friday.

Under section 512(c)(2)(F)(ii) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b(c)(2)(F)(ii)), this approval qualifies for 3 years of marketing exclusivity beginning November 4, 2002.

The agency has determined under 21 CFR 25.33(d)(1) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

This rule does not meet the definition of "rule" in 5 U.S.C. 804(3)(A) because it is a rule of "particular applicability." Therefore, it is not subject to the congressional review requirements in 5 U.S.C. 801–808.

List of Subjects

21 CFR Part 510

Administrative practice and procedure, Animal drugs, Labeling, Reporting and recordkeeping requirements.

21 CFR Part 524

Animal drugs.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under the authority delegated to the Commissioner of Food and Drugs and redelegated to the Center for Veterinary Medicine, 21 CFR parts 510 and 524 are amended as follows:

PART 510—NEW ANIMAL DRUGS

1. The authority citation for 21 CFR part 510 continues to read as follows:

Authority: 21 U.S.C. 321, 331, 351, 352, 353, 360b, 371, 379e.

2. Section 510.600 is amended in the table in paragraph (c)(1) by alphabetically adding an entry for "RMS Laboratories, Inc." and in the table in paragraph (c)(2) by numerically adding an entry for "067292" to read as follows:

§ 510.600 Names, addresses, and drug labeler codes of sponsors of approved applications.

* * * * *

(c) * * *

(1) * * *

Firm name and address	
• • • • •	
RMS Laboratories, Inc., 1903 East First St., Vidalia, GA 30474.	067292
• • • • •	

(2) * * *

Drug labeler code	
• • • • •	
067292	RMS Laboratories, Inc., 1903 East First St., Vidalia, GA 30474
• • • • •	

PART 524—OPHTHALMIC AND TOPICAL DOSAGE FORM NEW ANIMAL DRUGS

3. The authority citation for 21 CFR part 524 continues to read as follows:

Authority: 21 U.S.C. 360b.

4. Section 524.2482 is added to read as follows:

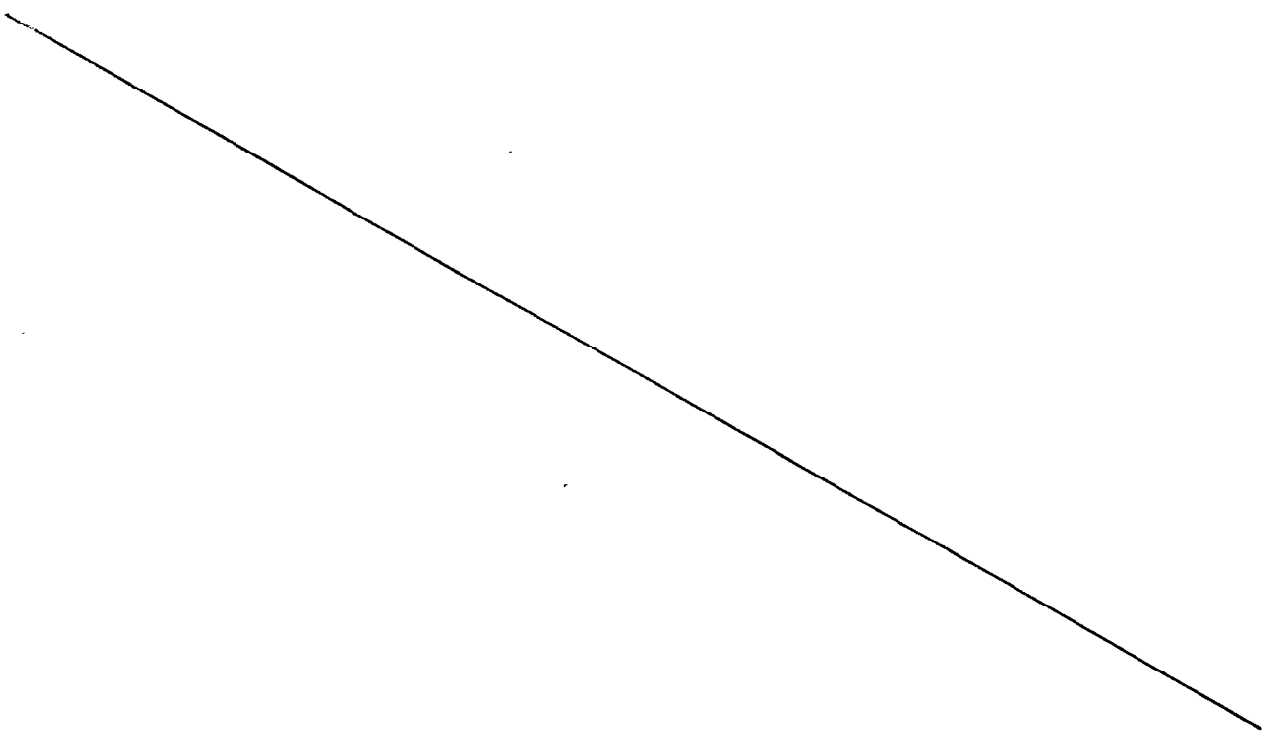
§ 524.2482 Triamcinolone spray.

(a) *Specifications.* Each milliliter of solution contains 0.15 milligrams triamcinolone acetonide.

(b) *Sponsor.* See No. 067292 in § 510.600(c) of this chapter.

(c) *Conditions of use in dogs*—(1) *Amount.* Apply sufficient pump sprays to uniformly and thoroughly wet the affected areas while avoiding run off of excess product. Administer twice daily for 7 days, then once daily for 7 days, then every other day for an additional 14 days (28 days total).

(2) *Indications for use.* For the control of pruritus associated with allergic dermatitis.



(3) *Limitations.* Federal law restricts this drug to use by or on the order of a licensed veterinarian.

Dated: 1/10/03
January 10, 2003.

Stephen F. Sundlof,
Director,
Center for Veterinary Medicine.

LB
1-16-03

[FR Doc. 03–????? Filed ??–??–03; 8:45 am]

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